

*Panel Discussion* ■

## Federal Patient Safety Initiatives Panel Summary

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### Introduction

The participants in this panel described major federal initiatives aimed at improving patient safety. Summaries of the panelists' remarks follow in the order of presentation at the Symposium.

### Summaries

#### Food and Drug Administration (FDA)

Medication errors have multiple causes including: poor communication, name confusion, abbreviations, poor techniques, knowledge deficit, inexperience, and confirmation bias. In addition to the patient, hospitals, practitioners, manufacturers, and governments can also be victims of medication errors. The FDA has collected more than 20,000 medication errors since 1993 and data reflect a 10% mortality rate. In order to combat medication errors, the FDA has initiatives in the area of pre-marketing, post-marketing, risk management, and research (Table 1). For more information see <<http://www.fda.gov/>>.

The FDA is involved in numerous risk communication activities including publishing in professional journals such as *AHSP*, *JAMA*, and *NEJM* and through the consumer-oriented *FDA Today*. Other risk minimization activities include improved labeling, letters to physicians, education, restricted access to a particular drug, and withdrawal from the

market. In addition, the FDA collaborates with other organizations such as the *AMA*, *AHSP*, *USP*, and *Institute for Safe Medication practices*.

Computer-based order entry is only a partial solution to medication errors. Other strategies are needed including pre-marketing testing in simulated environments, having drug information available at the point of information need, bar code use, and decision support systems that detect drug-drug and drug-disease interactions. Consequently, improving patient safety in the area of medication errors requires a multidisciplinary team effort.

#### VA National Center for Patient Safety

Stories from sites within and outside the Veterans Affairs (VA) system illustrate the frequency with which patient safety is compromised in health care settings. The National Center for Patient Safety (NCPS) embodies the VA's uncompromising commitment to reducing and preventing adverse medical

*Table 1* ■

#### Examples of Pre- and Post-Marketing FDA Activities Related to Patient Safety and Medication Error Prevention

##### Pre-Marketing Activities

- Analysis of potential name confusion including verbal and written tests
- Examination of phonetic similarities
- Labeling and packaging studies
- Risk/benefit analysis of proposed drug name

##### Post-Marketing Activities

- Adverse Events Reporting System (AERS) for surveillance and classification of errors
- Trend analysis

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events while enhancing the care given to patients. Activities include operations, training, and analysis and action. In addition to centralized resources such as analysts and software developers, each of 172 VA sites has a dedicated patient safety manager augmented by risk management and quality management personnel. Among the software products developed is an application that supports root cause analysis (see Williams et al., this issue). More than 1,000 persons have participated in NCPS's training program since its inception.

One example that illustrates the type of analysis and action undertaken by NCPS is MRI hazards. Near misses and fatalities have been reported as a result of ferromagnetic objects being pulled toward the magnetic bore at a rate of up to 40 miles per hour. Multifaceted intervention that includes both high-tech and low-tech solutions is necessary to decrease hazards. A summary of the MRI hazards report and recommendations as well as other information about NCPS is available at <<http://www.patientsafety.gov/>>.

### Patient Safety Reporting System (PSRS)

The Patient Safety Reporting System (PSRS) is a program being jointly developed by the Department of Veterans Affairs (VA) and the National Aeronautics and Space Administration (NASA) to discover and learn about issues related to patient safety through a voluntary, confidential reporting system. Modeled upon the Aviation Safety Reporting System (ASRS), the PSRS seeks to transfer the lessons learned from the aviation industry to health care. Such an early warning system is necessary in order to understand where the system failed the person and the person failed using the system and to shore up existing loopholes. The 1974 airline crash of a 727 in Washington, DC was the airline industry's equivalent of the IOM report. Since that time more than 500,000 reports have been submitted to ASRS without violating the identity of the reporter.

Through PSRS, VA staff members at the "sharp end" (including non-paid personnel such as students) are invited to share their stories by completing a narrative report. PSRS is designed to come at safety and human error from a different perspective. Key factors to PSRS include:

- Voluntary participation
- Protection of confidentiality
- Non-punitive

Table 2 ■

### Examples of Information Technology Projects Funded Under AHRQ Patient Safety Initiatives

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Using Prospective MDS Data to Enhance Resident Safety  
 Impact of Electronic Prescribing on Medication Errors  
 Mining Complex Clinical Data for Patient Safety Research  
 Improving Safety by Computerizing Outpatient Prescribing  
 HIV Treatment Error Reduction Using a Genotype Database  
 Do Simulations Reduce the Time to Learn Clinical Skills?  
 Improved Patient Safety with Information Technology  
 Improving Primary Care Patient Safety with Handheld DSS

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PSRS is designed to interact with other safety-related strategies including procedures, policies, hardware, software, incident reports, root cause analyses, and other data sources to make successive improvements in patient safety. For more information see <<http://psrs.arc.nasa.gov/faq.htm>>.

### Agency for Healthcare Research and Quality (AHRQ)

Following the publication of "To Err is Human,"<sup>1</sup> there has been debate about the actual numbers of medical errors that occur, however, most agree that the number is too high. In a study sponsored by the Kaiser Family Foundation and AHRQ, 47% of the participants said they are "very concerned" about an error resulting in injury happening to them or their family when receiving health care in general.

As noted in "Crossing the Quality Chasm", health-care should be supported by systems that produce care that is safe, effective, patient-centered, timely, efficient, and equitable. Information technology has a critical role in the design of such systems.

Fitzmaurice et al.<sup>2</sup> recently summarized informatics research of relevance to patient safety AHRQ and its predecessors have funded for over three decades. Some of the more recent AHRQ initiatives are described by Ortiz (this issue) and include the following areas:

- Patient Safety Research Dissemination and Education
- The Effect of Health Care Working Conditions on Quality of Care
- Clinical Informatics to Promote Patient Safety
- Improving Patient Safety: Health Systems Reporting, Analysis, and Safety Improvement Research Demonstrations

- Centers of Excellence for Patient Safety Research and Practice
- Developmental Centers For Evaluation and Research In Patient Safety

Examples of specific information technology projects funded under these initiatives are shown in Table 2. For more information see <<http://www.ahrq.gov>>.

## Discussion

The activities described by the panel participants indicate an unprecedented level of commitment to patient safety and cooperation among federal agencies. Moreover, the participants' remarks highlighted the essential role of information technology and informatics expertise in enabling an information infrastructure

that supports safe healthcare. The continued participation of the medical informatics community toward achieving the healthcare system goals set forth in the 2001 IOM quality chasm report is required.

Based upon a presentation at the 2001 AMIA Annual Symposium.

## References ■

1. Institute of Medicine Committee on Quality of Health Care in America. *To Err is Human: Building a Safer System*. Washington, DC: National Academy Press; 1999.
2. Fitzmaurice JM, Adams K, Eisenberg J. Three decades of research on computer applications in health care: Medical informatics support at the Agency for Healthcare Research and Quality. *J Am Med Inform Assoc* 2002;9(2):144-160.
3. Institute of Medicine Committee on Quality of Health Care in America. *Crossing the Quality Chasm*. Washington, DC: National Academy Press; 2001.